

# EXHIBIT C

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## P R O C E E D I N G S

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2  
3 THE VIDEOGRAPHER: Good morning. This is  
4 the video deposition of Robert Niemann taken by  
5 counsel for the Defendant in the matter of In Re  
6 Pharmaceutical Industry Average Wholesale Price  
7 litigation in the United States District Court for  
8 the district of Massachusetts, MDL number 1456, Civil  
9 Action Number 01-CV-12257-PBS, held in the offices of  
10 Centers for Medicare & Medicaid Services at 7111  
11 Security Boulevard, Baltimore, Maryland on this date  
12 Friday, September 14th, 2007, at the time indicated  
13 on the video screen, 9:18 a.m.

14 My name is Ellen Hebert. I'm the legal  
15 video specialist. The court reporter is Sue  
16 Ciminelli. We are employed by Henderson Legal  
17 Services. Counsel will now introduce themselves and  
18 the parties they represent after which the court  
19 reporter will swear in the witness.

20 MR. COOK: Christopher Cook for Abbott  
21 Laboratories for Jones Day. I'm accompanied by  
22 project assistant Emily Watson.

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1 MS. REID: Sarah Reid from Kelley Drye on  
2 behalf of the Day Companies and the DOJ cases and  
3 also on behalf of Day and Mylan at cross notice  
4 states.

5 MS. MCGEE: Jennifer McGee, representing  
6 Aventis Pharmaceutical and Sanofi.

7 MR. JONES: Scott Jones from Locke Liddell  
8 from Schering & Warrick.

9 MR. HOVAN: Aaron Hovan from Kirby  
10 McNerney, representing New York City and all New York  
11 counties other than Nassau and Orange.

12 MR. WILSON: Joe Wilson with Cotchett,  
13 Pitre & McCarthy, on behalf of Ven-A-Care.

14 MS. STAFFORD: Leslie Stafford of the  
15 Centers for Medicaid Services.

16 MS. OBEREMBT: Laurie Oberembt from the  
17 United States Department of Justice representing the  
18 United States.

19 THE VIDEOGRAPHER: Will the attorneys on  
20 the phone --

21 MR. BATES: I'm Roger Bates representing  
22 the State of Alabama.

00003

1 MR. GORTNER: Eric Gortner, representing  
2 from Kirkland & Ellis representing Boehringer  
3 Ingelheim and Roxane Laboratories Inc.

4 MR. ARCHIBALD: Jeff Archibald,  
5 representing the attorney generals for the states of  
6 South Carolina, Wisconsin, Kentucky, Iowa, and Idaho.

7 MS. MILLER: This is Mary Miller,  
8 assistant attorney general representing the State of  
9 Florida in the cross notice deposition cross noticed  
10 by Mylan.

11 MS. KAWATRA: Sandhya Kawatra from Hogan &  
12 Hartson representing Bristol-Myers Squibb Company.

13 MS. KATCHERIAN: Amy Katcherian, White &  
14 Case LLP, representing Sandoz, Inc.

15 MR. GLASER: Deputy attorney general Randy  
16 Glaser with the California Attorney General's Office

4369.txt

2 A. That's what it says.

3 Q. Or I assume other drugs, it says these  
4 drugs in the plural, correct?

5 A. That's what it says, yes, to price these  
6 drugs.

7 Q. Was it your understanding that it was the  
8 policy of HCFA that carriers were not permitted to  
9 obtain invoices and try to establish an estimated  
10 acquisition cost?

11 A. Well, I forgot that. But now that I'm  
12 reading this, I do seem to remember, I remember there  
13 were OMB requirements about data collection from more  
14 than a certain threshold number of people, and there  
15 was a process to go through in order to have that  
16 data collection approved and I do vaguely, not the  
17 details but I vaguely remember this coming into play  
18 with EAC so that, that seems to be what they are  
19 getting at here is that the data collection  
20 requirement had not been cleared through OMB. I  
21 think they said information collection is probably  
22 what they used.

00169

1 Q. Do you recall whether HCFA made efforts to  
2 satisfy those requirements to conduct surveys and  
3 establish estimated acquisition costs?

4 A. I don't.

5 Q. What was your understanding of what  
6 estimated acquisition cost would have represented had  
7 HCFA implemented that, that provision of the  
8 regulation?

9 A. Well, I would have -- I take that term at  
10 its literal meaning. I mean, it would, it would have  
11 been an estimate of what the cost was to the  
12 physician who is billing us, what that physician  
13 paid.

14 Q. And was it your understanding that had  
15 HCFA implemented that aspect of the regulation that  
16 HCFA would have attempted to establish it drug by  
17 drug?

18 MS. OBEREMBT: Objection.

19 THE WITNESS: I --

20 BY MR. COOK:

21 Q. I guess there is only one way to do it, it  
22 would have to be on a drug by drug basis correct?

00170

1 A. I guess that's true. I guess so.

2 Q. And in the Exhibit 310 which appears to  
3 be, would you agree with me, Dr. Steffen's response  
4 to the July 1996 letter? The first paragraph in this  
5 letter to Ms. Merrill states "we agree that the  
6 central office should be made aware of the issues  
7 that we discussed, namely the great difference  
8 between the EAC and the AWP the barriers to obtaining  
9 the EAC." Do you understand in that letter the EAC  
10 referred to acquisition costs as indicated in the Re  
11 line?

12 A. I don't but oh, right. Yes.

13 Q. Would you have been the individual within  
14 the central office who you assume would be made aware  
15 of the great difference between acquisition costs and  
16 the AWP for Medicare reimbursable drugs?

17 A. Yes.

18 Q. Did you participate in to your

4369.txt

19 recollection this conversation between Ms. Merrill  
20 and Dr. Steffen?

21 A. I don't remember that I did. No.

00171

22 Q. You'll see a little bit farther down the

1 page Dr. Steffen calculates some, some numbers for  
2 Zoladex, in particular and calculates that for  
3 provider with --

4 A. Can I -- something is troubling me.

5 Q. Please do.

6 A. Of a former, when you asked me the only  
7 way to implement AEC would have been on a drug by  
8 drug basis and I said I guess so because I'm not used  
9 to thinking about these things and thinking them  
10 through.

11 Q. Oh no please?

12 A. I don't think that would be true.

13 Q. How would one do it?

14 A. No. I have no idea how it could be done  
15 and the range of possibilities.

16 Q. Uh-huh?

17 A. But I would think the EAC could be used in  
18 combination to come up with a price for a HCPCS code  
19 that represented a range of suppliers for a drug.  
20 All I'm getting at is I didn't want to be locked into  
21 speculating that the only way EAC could be used was  
22 on a specific drug by drug basis. I don't want to

00172

1 agree to that because I don't know that to be true.

2 Q. Well, between 1993 and 1997, when you were  
3 the program, the policy analyst who was response for  
4 drug payment issues at Medicare, the regulation was  
5 still extant, correct that had EAC as one of the  
6 options, correct?

7 A. Yes.

8 Q. Did you consider any of the ways in which  
9 Medicare could have implemented the EAC option?

10 A. I don't remember that that ever, we never  
11 got that far.

12 Q. And how so?

13 A. Well, for the reasons we are saying, that  
14 either because of resources or because the  
15 information collection hurdle was never overcome, so  
16 we didn't have the data so I don't remember us ever  
17 having to consider that.

18 Q. So as I understand the position then of  
19 when I say the position, I don't mean the poll  
20 circumstances I mean the position that HCFA found  
21 itself in between 1991 and 1997 was it was paying  
22 with a Medicare allowable based upon AWP, correct?

00173

1 A. Uh-huh.

2 Q. It did not have, HCFA did not have in  
3 place any limitations on provider's charges, it would  
4 have prevented providers from charging more than  
5 their cost or more than a percentage over their cost,  
6 correct?

7 A. It's how I remember it.

8 Q. Right. That HCFA had one alternative of  
9 estimated acquisition costs that would have allowed  
10 it if implementable to gauge the Medicare allowable  
11 amount to something closer than to actual acquisition  
12 cost, correct?

4369.txt

13 A. Yes.  
 14 Q. Was it your sense that HCFA as an  
 15 organization wanted to move towards EAC?  
 16 MS. OBEREMBT: Objection.  
 17 THE WITNESS: I don't know how to answer  
 18 that. I mean, how many people would have been  
 19 involved in this and what their opinions would have  
 20 been, I never polled anybody.  
 21 BY MR. COOK:  
 22 Q. Okay. Was there anybody within the agency

00174

1 who preferred to stay with AWP rather than go to EAC  
 2 in your memory?  
 3 MS. OBEREMBT: Objection to the extent  
 4 you're asking him about deliberative process  
 5 conversations.  
 6 THE WITNESS: So what do I do?  
 7 MS. OBEREMBT: Why don't we take a break  
 8 and let me find out what he was going to say.  
 9 MR. COOK: Okay.  
 10 THE VIDEOGRAPHER: This marks the end of  
 11 tape three in the deposition of Robert Niemann. The  
 12 time is 13:54:38.  
 13 (Recess.)  
 14 THE VIDEOGRAPHER: This marked the  
 15 beginning of tape four in the deposition of Robert  
 16 Niemann. Going back on the record. The time is  
 17 14:02:57.  
 18 MS. OBEREMBT: Chris, I understand your  
 19 question to be asking him about discussions he had  
 20 with others at CMS about what the drug policy should  
 21 be.  
 22 MR. COOK: Yes.

00175

1 MS. OBEREMBT: So on that basis I'm going  
 2 to instruct him not to answer because it does go to  
 3 deliberative process.  
 4 MR. COOK: And just so I know the  
 5 parameters of the instruction not to answer, to the  
 6 extent that there was anybody within CMS who actually  
 7 preferred to go with, stay with AWP knowing that AWP  
 8 exceeded acquisition costs rather than going to EAC  
 9 which would approximate acquisition cost you're going  
 10 to instruct him not to answer those questions?  
 11 MS. OBEREMBT: I'm going to instruct him  
 12 not to disclose discussions he had about what a  
 13 policy should be because that goes to the heart of  
 14 the deliberative process privilege.  
 15 MR. COOK: Well, I'll ask him a question  
 16 and you can instruct him not to answer because I want  
 17 this one to be, I want to know what I can ask and  
 18 what I can and I'll just go through the questions and  
 19 you can instruct him not to answer them if you think  
 20 that they are not, that they are not permissible.  
 21 BY MR. COOK:  
 22 Q. Mr. Niemann, you understood that there

00176

1 were essentially two options available to the  
 2 Medicare program between 1991 and 1997 for  
 3 establishing what the Medicare allowable should be or  
 4 would be for physician administered drugs, correct?  
 5 It's restating an earlier question. I know.  
 6 A. On the allowable, it's really technically

4369.txt

7 I guess three.

8 Q. Okay?

9 A. Because we pay the lower of the actual  
10 charge on the thing.

11 Q. All right. But there will always be a  
12 charge in connection with the claims for physician  
13 administered drug correct?

14 A. Right.

15 Q. And the question is going to be if that  
16 charge exceeds a certain amount, will you pay the  
17 charge or that certain amount, correct?

18 A. Right.

19 Q. So if, for example, the charge is, well I  
20 guess the last data point in any claim would be the  
21 actual cost to the physician, correct, although  
22 that's not one that you have.

00177

1 A. Well, all I was saying is that there are  
2 three.

3 Q. Right?

4 A. Components to the decision.

5 Q. Correct. And if we were to look at an  
6 individual claim, there would be four, there would be  
7 three data points, one would be the physician has an  
8 actual cost, correct?

9 A. Right.

10 Q. You don't know what that is?

11 A. Right.

12 Q. The physician states a charge to the, the  
13 program, correct?

14 A. Right.

15 Q. You Doe know what that number is?

16 A. Yes.

17 Q. And the program through its carriers has  
18 an allowable amount which the charge may not exceed  
19 or will be disallowed to the extent that it exceeds  
20 the allowable, correct?

21 A. They wouldn't pay any more than that.

22 Q. Right. There were two options for the

00178

1 program to set what the allowable amount would be  
2 under the Medicare regulations as they existed  
3 between 1991 and 1997, correct?

4 A. Yes. I would just say I recognize you're  
5 struggling. The maximum allowable.

6 Q. Precisely?

7 A. Because it would never exceed the actual  
8 charge.

9 Q. Precisely.

10 A. I get the drift of what you're saying.

11 Q. And the two options for setting the  
12 maximum allowable would be 100 percent of the maximum  
13 allowable as published in Red Book or other compendia  
14 right?

15 A. Or other compendia.

16 Q. That's right?

17 A. I think that's what it said.

18 Q. The other option under the Medicare  
19 program under the regulations was to establish an  
20 estimated acquisition cost, correct?

21 A. Yes.

22 Q. Unlike the average wholesale price, that

00179

4369.txt

1 would be a calculated number, correct?

2 A. Yes.

3 Q. It would be calculated by HCFA?

4 A. I --

5 Q. Or the carriers?

6 A. Yes. I think the carriers.

7 Q. By either HCFA for its agent?

8 A. Right.

9 Q. Would calculate that number correct?

10 A. Yes.

11 Q. And do you have an understanding of how  
12 hick have or its agents would calculate that number?

13 A. No.

14 Q. Do you have an understanding of what that  
15 number would represent?

16 A. Oh as I said before, I think it would be  
17 the best estimate of what the physician's acquisition  
18 cost was but I don't necessarily mean that individual  
19 physician.

20 Q. And in choosing between the published  
21 average wholesale price and the best estimate of what  
22 the physician's acquisition cost was, that is

00180

1 estimated acquisition cost, did you have any  
2 discussions within the agency about which option to  
3 use?

4 MS. OBEREMBT: You can answer that. You  
5 can tell him whether or not you had discussions about  
6 options.

7 THE WITNESS: Yes.

8 BY MR. COOK:

9 Q. And were there individuals who advocated  
10 for staying with the average wholesale price?

11 MS. OBEREMBT: I'll direct you not to  
12 answer that on the grounds of deliberative process.

13 MR. COOK: So I can't get the process of  
14 whether there were individuals who took that  
15 position.

16 MS. OBEREMBT: That's right. Because  
17 because that goes to the substance of the  
18 discussions. Your previous went to whether or not  
19 there were discussions now you're getting into the  
20 substance so I have to object.

21 BY MR. COOK:

22 Q. Were there individuals who advocated using

00181

1 the estimated acquisition cost?

2 MS. OBEREMBT: Objection. Grounds of  
3 deliberative process. I'll direct you not to answer.

4 BY MR. COOK:

5 Q. Who participated in these discussions?

6 A. It would have been my division director,  
7 me and the deputy group director. Legislative  
8 personnel on our legislation staff. I don't mean, I  
9 don't mean staffers on the Hill. I mean our people.  
10 People like that.

11 Q. When did these conversations take place?

12 A. I guess off and on for the whole time that  
13 I was involved in it. Maybe not, not too early. I  
14 don't have that clear recollection of --

15 Q. As a matter of fact, for the entire time  
16 period where estimated acquisition cost was an option  
17 available to HCFA, HCFA in fact established its

4369.txt

18 maximum allowable cost based upon average wholesale  
19 price, correct?

20 A. Yes. Except where a carrier may have done  
21 it sooner than when this all came about with OMB and  
22 the information collection.

00182

1 Q. In any of these discussions, do you recall  
2 any participant ever expressing to you the belief  
3 that by paying average wholesale price Medicare  
4 program was reimbursing physicians at their actual  
5 acquisition cost?

6 MS. OBEREMBT: Objection on the grounds of  
7 deliberative process. I'll instruct you not to  
8 answer.

9 BY MR. COOK:

10 Q. Has anybody ever in your time at HCFA  
11 expressed to you the belief that average wholesale  
12 price is a reliable indicator of the acquisition cost  
13 to physicians for drugs?

14 MS. OBEREMBT: I'm going to object to the  
15 extent you're asking him about conversations he had  
16 that involve deliberative processes of the agency.  
17 I'm going to instruct you not to answer that too.

18 BY MR. COOK:

19 Q. In any of these conversations relating to  
20 the possibility of abandoning AWP and going to  
21 estimated acquisition cost, did any of the  
22 individuals that you've described ever raise concerns

00183

1 about what the consequences would be to beneficiaries  
2 access to care or other program goals of going to  
3 EAC?

4 MS. OBEREMBT: Objection on the grounds of  
5 the deliberative process privilege. I'll instruct  
6 you not to answer.

7 BY MR. COOK:

8 Q. What position did you take about using  
9 average wholesale price or the estimated acquisition  
10 cost?

11 MS. OBEREMBT: Objection on the grounds of  
12 deliberative process. I'll instruct you not to  
13 answer.

14 BY MR. COOK:

15 Q. Did politics ever play a role in the  
16 Medicare program's decision to continue to use  
17 average wholesale price rather than use estimated  
18 acquisition costs to establish its maximum allowable  
19 payment amount for drugs?

20 MS. OBEREMBT: Objection to the extent  
21 you're asking him about discussions with agency  
22 personnel where a policy decision was made. I have

00184

1 to instruct you not to answer that too, I think.

2 BY MR. COOK:

3 Q. At various points in time between 1991 and  
4 1997 without telling me about what discussions were  
5 made, is it fair to say the decision was made to stay  
6 with AWP and not go to estimated acquisition cost?

7 A. Well that was the stated, that was the  
8 regulation.

9 Q. Well the regulation allowed both?

10 A. Oh, allowed both?

11 Q. Yes?

4369.txt

12 A. I'm sorry would you repeat.  
 13 Q. I assume -- at various points in time when  
 14 the possibility of going from AWP to EAC was  
 15 considered?

16 A. Right.  
 17 Q. In fact, HCFA continued to use AWP,  
 18 correct?

19 A. It did.  
 20 Q. All right. After discussions relating to  
 21 a possible change and after it was decided to remain  
 22 with AWP, did you ever have any discussions with any

00185

1 other personnel at HCFA about the decision that had  
 2 already been made to stay with AWP and whether that  
 3 was a good idea?

4 MS. OBEREMBT: Objection because again I  
 5 think you don't have a specific point demarche ated  
 6 and his post policy discussions may be predecisional  
 7 to subsequent policies so I can't, I'm going to  
 8 object again on deliberative process and instruct you  
 9 not to answer.

10 BY MR. COOK:

11 Q. Did you ever have any discussions with  
 12 anyone outside of HCFA about whether Medicare could,  
 13 should continue to pay based upon AWP or should use  
 14 some other methodology for establishing the maximum  
 15 allowable amount?

16 A. That I don't remember. Outside of HCFA.

17 Q. Yes?

18 A. I don't remember.

19 Q. Say someone with Congress?

20 A. That would have occurred. I can't  
 21 remember specifically, but that would have occurred.

22 Q. Without the specifics?

00186

1 A. Not a member of Congress but the staffer.

2 Q. The staffer. Do you remember generally  
 3 what the subject matters were relating to the  
 4 possible departure from AWP as a methodology in your  
 5 conversations with congressional staffers?

6 A. I'm sorry. What was the -- what's the  
 7 crux of that? Do I remember what.

8 Q. Do you remember generally what the subject  
 9 matters of those conversations were?

10 A. Subject matters?

11 Q. Let me ask it a little bit easier. Do you  
 12 remember anything at all about your conversations  
 13 with congressional staffers?

14 A. That is easier. Not much, but it would,  
 15 it would have been the IG information and some kind  
 16 of methodology to pay a fair price.

17 Q. Do you recall whether you or anybody else  
 18 from HCFA was advocating a change in the methodology  
 19 to these congressional staffers?

20 MS. OBEREMBT: You can answer that.

21 THE WITNESS: Was anybody advocating a  
 22 change to what the staffers were recommending? I'm

00187

1 sorry.

2 BY MR. COOK:

3 Q. The status quo was that?

4 A. AWP and we never implemented AEC. That  
 5 was the status quo.

4369.txt

6 MS. OBEREMBT: Are you asking him in his  
7 conversations with people on the Hill?

8 MR. COOK: Yes.

9 MS. OBEREMBT: Okay. So focus your answer  
10 on just conversations you had with people on the  
11 Hill, what was said.

12 THE WITNESS: Not HCFA people but  
13 staffers.

14 MS. OBEREMBT: Right.

15 BY MR. COOK:

16 Q. Right. Did you or anybody else from HCFA  
17 in these conversations with staffers on the Hill ever  
18 advocate a change in the methodology away from AWP?

19 A. Yes. Yes.

20 Q. What?

21 MS. OBEREMBT: Objection. That goes to a  
22 deliberative process issue since you're asking him

00188

1 why they would have expressed that opinion to the  
2 staffers.

3 MR. COOK: So the decision was whether to  
4 talk to Congress.

5 MS. OBEREMBT: You can ask him what was  
6 said to the staffers, but you can't ask him why that  
7 was said because that does go to deliberative process  
8 information okay.

9 MR. COOK: Just so I understand and I've  
10 got the record straight. Exactly which decision is  
11 that deliberation predecisional to?

12 MS. OBEREMBT: To decisions made within  
13 the agency to either continue with the existing  
14 policy or to proceed with change in policy so why  
15 don't don't you ask him what he said to the staffer  
16 or was he present in any other HCFA meeting with a  
17 congressional staffer.

18 BY MR. COOK:

19 Q. Did you express to the congressional  
20 staffers why it was that HCFA was advocating a change  
21 in the methodology by which Medicare paid for  
22 physician administered drugs?

00189

1 A. Yes. I'm sure I would have expressed the  
2 reason.

3 Q. And what was that reason?

4 A. It would have been the IG reports if the  
5 fact that, that at least some of the drugs under the  
6 AWP policy were, were, we were paying too much.

7 Q. When you say too much, can you quantify  
8 that for me?

9 A. No, I can't quantify it because of the  
10 reason you have cited that it wasn't a single amount  
11 with every drug. It varied.

12 Q. When you say too much, is that a dollar  
13 amount, a percentage?

14 A. I remembered that being some concern. And  
15 remember being released that I wasn't the one who had  
16 to pick the number. I mean it's a judgment call  
17 what, like whether to knock off 5 percent or 15  
18 percent, that's a judgment call.

19 Q. And 10 percent of a \$400 drug is a lot  
20 more than a thousand percent of a \$2 drug, correct?

21 A. Indeed it is.

22 Q. Did you express to Congress any position